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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,010

09/15/2003

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33205.0800

1757

20322 7590 12/08/2009
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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: We discussed the ASTM # recited in Applicants' claims. Ms. Pillote indicated that to find the recited ASTM # one must search the American National Standards Institute (ANSI) website using "D-1824", wherein the "-87" indicates that the ASTM # recited in the claims is the 1987 standard.. Applicants' counsel indicated that they would provide evidence that the ASTM D1824-87 standard is publicly available for purchase from ANSI. The Examiner searched the ANSI website during the interview and found the ASTM D1824-95 listing with the associated purchase price (a copy of the websearch hit is provided with this interview summary). Upon Applicants' providing evidence that the ASTM D1824-87 standard for measuring viscosity is publicly available, the Examiner believes that the 112, 2nd rejection of record will be overcome.

We discussed that Haslwanter's disclosure describes a "complex viscosity" (e.g. col. 4, lines 47-65; Figure 2; and Example 5). Applicants' counsel believes that the complex viscosity values taught by Haslwanter would be different than the viscosity values recited in Applicants' claims as measured according to the ASTM D1824-87 standard. The Examiner indicated that to support the argument that Haslwanter's complex viscosity values do not overlap with the viscosity values recited in Applicants' claims it would be helpful to provide comparison viscosity data of Haslwanter's compositions, such as is described in Haslwanter's Example 5, wherein the viscosity of Haslwanter's compositions was measured using the ASTM D1824-87 standard.

Ms. Pillote indicated that the amount of liposomes taught by the secondary reference, Sundgren, or 20-80% lipids in paragraph [0607] was far outside the range of about 0.00001 to about 5.0 % w/w recited in Applicants' claim 30. The Examiner agrees with this observation regarding the amount recited in Sundgren's paragraph [0607], but that he would calculate the weight percent for the amount of liposome lipid specified in Example 19.3 of Sundgren in paragraph [0608]. Assuming that the calculated weight amount of liposome in Sundgren's Example 19.3 is outside the range recited in Applicants' claim 30, the Examiner agrees that this would overcome the rejection of claim 30 and claims dependent therefrom.

Ms. Pillote indicated that Applicants would amend claim 40 and claims dependent therefrom to recite "consisting of" instead of "consisting essentially of" and to recite specific thickeners to distinguish these claims from the teachings of Haslwanter, which indicate that Haslwanter's compositions in part consist essentially of (i) microcrystalline cellulose (i.e. a thickener) and (ii) an alkali metal carboxyalkylcellulose (e.g. AVICEL RC-591) (see abstract; col. 2, lines 45-54; and Examples 1-3: col. 5, line 34 through col. 7, line 13). The Examiner indicated that the aforementioned amendments to claim 40 and claims dependent therefrom should overcome the rejection based on Haslwanter.

Ms. Pillote requested that upon submission of the aforementioned amendments in a reply that the Examiner withdraw finality. The Examiner indicated that finality will not be withdrawn at this time, but that Applicants should submit an after final response with the aforementioned amendments and that he would consider said amendments.

Ms. Pillote requested a supplemental interview upon submission of the above requested documents (e.g. evidence that the ASTM 1987 standard is still publicly available). The Examiner agreed to a supplemental interview early next week (i.e. week of December 7th) to be scheduled next week.